

**Quality System Assessment of the Region 7  
Drinking Water Laboratory Certification Program**

**by the**

**Office of Ground Water and Drinking Water  
Technical Support Center**

**November 18, 2009**

**U. S. ENVIRONMENTAL PROTECTION AGENCY**

**Cincinnati, Ohio 45268**

## **Introduction**

The *Manual for the Certification of Laboratories Analyzing Drinking Water* (LCM), Fifth Edition, EPA 815-R-05-004, 2005, requires the Office of Ground Water and Drinking Water (OGWDW) to “review the Regional drinking water certification programs annually and evaluate the resources and personnel available in each Region to carry out the certification program.” Paper reviews in the form of questionnaires are done annually with on-site assessments conducted triennially. Judy Brisbin and Jennifer Best of the Technical Support Center (TSC) performed a Quality System Assessment (QSA) of the Region 7 Drinking Water (DW) Laboratory Certification Program (LCP) on October 20-22, 2009 at the Region 7 Science & Technology Center in Kansas City, KS. The on-site evaluation is conducted to assess the adherence of the EPA Regional Certification Authority to the requirements of the LCM Chapters I – III. The QSA included a review of documents and discussions with Lawrence (Larry) Marchin, Laboratory Certification Program Manager (LCPM) for Region 7.

## **Quality and Timeliness of State Laboratory Audits**

Principal State Laboratory (PSL) audits for Chemistry, Microbiology and Radiochemistry are to be conducted on a 3-year cycle as described in the LCM. Along with PSL audits, assessment of the State LCP should be performed, as outlined in Chapter III of the LCM. The table below gives the last dates audits were performed of the PSLs and drinking water LCPs for the States in Region 7.

STATE	LAST AUDIT OF PRINCIPAL STATE CHEM LAB	LAST AUDIT OF PRINCIPAL STATE MICRO LAB	LAST AUDIT OF PRINCIPAL STATE RAD LAB	LAST DW LAB CERT PROGRAM AUDIT
IA	01/2009 CA-NELAP	01/2009 CA-NELAP	01/2009 CA-NELAP	Questionnaire: 04/2009  On-site: 11/2006
KS	10/2006	04/2009	09/2009 CSC - contractor	Questionnaire: 04/2009 NELAC AB On-site: 5/2008
MO	09/2008	04/2009	10/2009 CSC - contractor	Questionnaire: 04/2009  On-site: 08/2007
NE	09/2007	05/2007	N/AP [WY Lab in Region 8 FL-NELAP]	Questionnaire: 04/2009  On-site: 9/2007

- IA: University of Iowa Hygienic Laboratory, Iowa City, IA - Chemistry, Microbiology and Radiochemistry. Also, University of Iowa Hygienic Laboratory, Ankeny, IA – Chemistry. Certification for all PSLs are done by NELAP.
- KS: Kansas Department of Health & Environment, Forbes Field, Topeka, KS – Chemistry, Microbiology and Radiochemistry. Certification for Radiochemistry is contracted out to CSC. [Note: Kansas is a NELAC AB.]
- MO: Missouri Department of Natural Resources Laboratory, W. Main Street, Jefferson City, MO – Chemistry. State Public Health Laboratory, N. Chestnut Street, Jefferson City, MO and State Public Health Laboratory, SE, Poplar Bluff, MO – Microbiology. St. Louis County Health Laboratory, Clayton, MO - Radiochemistry. Certification for Radiochemistry is contracted out to CSC.
- NE: Public Health Environmental Laboratory, S. 14<sup>th</sup> Street, Lincoln, NE – Chemistry and Microbiology. Some Chemistry analysis is contracted to NELAP Laboratories. Energy Laboratory, Inc., Wyoming - Radiochemistry.

State PSLs in Region 7 are audited every three years. Details of Region 7's Protocols for the Certification of PSLs to Perform Drinking Water (DW) Analysis are included in Standard Operating Procedure (SOP) No. 1350.4C *Certification of Drinking Water Laboratories in Region 7*. The SOP describes Region 7's policies and procedures for such elements of the LCP as: Proficiency Testing (PT) studies, on-site assessment of the State Laboratory, and issuance of yearly Certificates.

The Region 7 LCP is up-to-date in conducting onsite evaluations of all of the PSLs within Region 7. Onsite evaluations of the Kansas and Missouri Radiochemistry PSLs were recently conducted with the assistance of an OGWDW contractor. The Kansas Chemistry PSL audit has been scheduled for the first week of November, 2009. There are no Tribal Nations with DW Laboratories or DW Programs in Region 7.

Region 7 is to be commended for the quality of the onsite evaluation reports. The OGWDW team (OGWDW team) noted that a 2009 microbiology evaluation report prepared by Ms. Isabel Velasquez was detailed and thorough and represents an improvement over previous reports.

### **Reviews of State Certification Programs**

TSC sends an annual questionnaire to all of the Regional LCPMs regarding the status of the certification program in the States within their Region. Mr. Marchin modifies this questionnaire and sends it to the States in Region 7. This modified questionnaire serves as an annual program review for the States in Region 7, while on-site evaluations of the State DW Programs are conducted by the Region 7 LCP staff on a triennial basis. The procedure for conducting these program reviews is outlined in SOP No. 1350.05B *Oversight and Evaluation of the State Drinking Water Laboratory Certification Programs*. The Region 7 SOP details the elements reviewed at the on-site LCP reviews.

The Region 7 LCP has kept on schedule and is current with all State Certification Program reviews. The Region 7 LCP staff is to be commended for quality of the LCP reports. The OGWDW team noted that the reports were very detailed and included significant technical detail; it is evident that Region 7 is conducting very thorough reviews of the State LCPs. The OGWDW team noted that Region 7 encourages the States to participate in ethics training, and urges Region 7 to continue to promote this.

The IA PSL failed the Radiochemistry parameter Gamma emitters and CA-NELAP subsequently withdrew their certification. The OGWDW team did not find corrective action in the file. Mr. Marchin stated that Iowa has since passed a PT. He is checking to see if CA-NELAP has reinstated Iowa's certification. Corrective actions for the last MO program review were not in the MO file. Mr. Marchin is confirming that MO has responded appropriately.

The OGWDW team commends Region 7 for participating in an onsite evaluation with each of the State Certification Officers (COs) as a part of the LCP evaluation. While we recognize this practice as outstanding, the OGWDW team noted that the Region 7 LCP assessment team typically consisted only of Larry Marchin and Barry Evans, both of whom are chemistry COs, shadowing microbiology laboratory evaluations. The OGWDW team noted that it would be more effective if one of the Region 7 microbiology COs were to shadow the State COs on future microbiology LCP evaluations.

Additionally, the OGWDW team noted that some of the COs in some of the Region 7 States had not participated in any refresher training for quite some time (specifically, IA had several COs that have not had refresher training for many years). OGWDW encourages both the Regional and State COs to return to the CO training courses approximately every five years for refresher training. Refresher training serves to update the COs on any new regulations and methods that may have been promulgated since they last attended the training, but additionally serves as a review of other methods and regulations.

## **Regional Certification Program Files**

Files from all of the States in Region 7 were reviewed and found to be well organized. Mr. Marchin is doing a great job maintaining the files. The OGWDW team noted that the organization and content of the State files has improved since the last OGWDW onsite evaluation in 2006. All State files contained copies of the most recent certificates along with a list of methods and analytes for which the laboratory was granted certification. Region 7 is to be commended for the format of the certificates, as the certificates were designed in such a way that it was very easy to identify the analytes and methods for which the laboratory was certified. Region 7 also includes an expiration date on all certificates, which is a practice that OGWDW has been recommending to all Regional programs. The files also contained examples in which the States informed Mr. Marchin of changes in State laboratory personnel and equipment changes in the laboratories. There were multiple copies of some documents in the Program files that could be removed. The OGWDW team would like to see copies of technical direction/communication with the States kept in the files, especially if it involves policy implications or interpretations. Training files are maintained and PT results are entered and tracked in a separate database.

## **Communications with State Counterparts**

Region 7 holds conference calls on a quarterly basis with the States in Region 7. A conference/teleconference was held on October 21, 2009 in conjunction with the OGWDW team's on-site visit. Thirteen people were in attendance, including personnel from Region 7 and the States within Region 7. All of the States in Region 7 were represented.

Region 7 is to be commended for holding quarterly calls with the States certification program staffs within Region 7. This fosters communication and collaboration among the State programs and Region 7.

The OGWDW team noted that the State files contained many emails between the State LCPs and Mr. Marchin. These communications demonstrate that Mr. Marchin has established a strong relationship with his counterparts in the State programs. The OGWDW team noted that Region 7 worked with the State of KS recently when the State experienced turnover of key personnel and was having difficulty in filling the positions due to budget problems. KS did fill the key positions and now has adequate staffing for the certification program. Additionally, OGWDW would like to recognize that KS sent all new hires to both CO Training courses this year, an outstanding commitment to running a proficient LCP.

## Resources

Region 7 is to be recognized for their commitment to the LCP. It was evident to the OGWDW team that Region 7 has improved the program in recent years, and that they are committed to continual improvement. Region 7 is further recognized for recruiting two new microbiology COs.


The OGWDW team does recommend (as per the LCM), that all COs attend refresher training every five years. The OGWDW team noted that Mr. Marchin and Mr. Evans have not had recent refresher training.

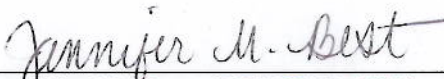
## RECOMMENDATIONS:

There are no mandatory corrective action items. Recommendations are as follows:

- Continue to encourage the States to receive ethics training; continue to address this in the program review reports.
- Locate/request documentation from IA concerning corrective action for the failed Radiochemistry parameter Gamma-emitters and place it in the IA file.
- Verify that MO had responded with corrective actions for the last program review and place this information in the MO file.
- Have Chemistry COs shadow chemistry audits and Microbiology COs shadow microbiology audits. If chemistry COs are needed to shadow microbiology audits they should complete the Microbiology COs Training Course.
- Have Larry Marchin, Barry Evans and several COs from Iowa audit the COs Training Course.
- Remove multiple copies of documents in the Program files.
- Keep copies of technical direction/communication with the States in the State program files, especially if they involve policy implications or interpretations.

Submitted November 18, 2009

  
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October 2009

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